

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA; STATES OF
CALIFORNIA, COLORADO, CONNECTICUT,
DELAWARE, FLORIDA, GEORGIA, HAWAII,
ILLINOIS, INDIANA, IOWA, LOUISIANA,
MICHIGAN, MINNESOTA, MONTANA,
NEVADA, NEW JERSEY, NEW MEXICO,
NEW YORK, NORTH CAROLINA,
OKLAHOMA, RHODE ISLAND, TENNESSEE,
TEXAS, VERMONT, AND WASHINGTON;
THE COMMONWEALTHS OF
MASSACHUSETTS AND VIRGINIA; AND
THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

v.

JANSSEN BIOTECH, INC., JANSSEN
ONCOLOGY, INC., JANSSEN RESEARCH &
DEVELOPMENT, LLC, JOHNSON &
JOHNSON, and BTG INTERNATIONAL
LIMITED,

Defendants.

Civil Action No.: 19-12107 (KM)(JBC)

Motion Return Date: February 7, 2022

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**PLAINTIFF-RELATOR ZACHARY SILBERSHER'S OPPOSITION
TO DEFENDANTS' MOTION TO CERTIFY INTERLOCUTORY APPEAL
AND FOR A STAY (DE 182)**

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INTRODUCTION

Plaintiff Zachary Silbersher’s Second Amended Complaint (DE 63)¹ alleges that Defendants committed fraud to cause the United States and Plaintiff States to pay hundreds of millions of dollars more for the prostate cancer drug Zytiga (abiraterone acetate) than they should have. Defendants² are thus liable under the False Claims Act (“FCA”), 31 U.S.C. § 3729.

Defendants filed a joint motion to dismiss on April 6, 2021 (DE 182), arguing that this case should be dismissed under the FCA’s public disclosure bar, 31 U.S.C. § 3730(e)(4). (Memorandum in Support of Defendants’ Joint Motion to Dismiss Second Amended Complaint (“MTD”), DE 182-1, at 7-22) Defendants also urged the Court to dismiss because the Complaint supposedly failed sufficiently to allege falsity or materiality. (*Id.*, at 23-37)

The Court denied Defendants’ motion by Order filed December 17, 2021 (DE 180) based on its Opinion filed the same day (DE 179). In its Opinion, the Court rejected Defendants’ argument that an *inter partes* review (“IPR”) proceeding is a “Federal . . . hearing” under channel (ii) of the public disclosure bar, 31 U.S.C. § 3730(e)(4)(A)(ii), because such a reading would nullify Congress’s 2010 amendments “limiting channel (i) to federal hearings to which the Government is a party.” (DE 179, at 14-15) The Court also rejected Defendants’ argument that “patent prosecution materials” that “were ‘published’ on the PTO’s Patent Application Information Retrieval (‘PAIR’) system” constituted “Federal report[s]” for purposes of the public disclosure bar. (*Id.*, at 15-16) Instead, the Court agreed with the decision in *Silbersher v. Allergan Inc.*, 506 F. Supp. 3d 772 (N.D. Cal. Dec. 11, 2020), *appeal pending* No. 21-15420 (9th Cir.), that this “argument would eviscerate Congress’s limitation of channel (i), rendering any federal proceeding with a public docket—regardless of whether or not the Government was a party—a permissible

¹ “DE” refers to docket entries. References to the “Complaint” are to the Second Amended Complaint (DE 63); Complaint citations are by paragraph number. Other documents are cited by docket and page number. Undefined capitalized terms have the meaning assigned in the Complaint. Citations to Defendants’ Memorandum in Support of Defendants’ Motion to Certify Interlocutory Appeal and for a Stay (DE 182-1) are to “Motion” or “Mot.”

² “Defendants” refers to Johnson & Johnson, Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC. For the purposes of this opposition, now-dismissed defendant BTG International Ltd. is excluded from “Defendants.”

channel that could trigger the public disclosure bar.” *Ibid.* (cleaned up). That “would make channel (i) superfluous and ignore Congress’s evident intent in amending it.” (DE 179, at 16) As the Court cogently explained, “Congress’s 2010 amendments were intended to narrow the definition of publicly disclosed information, not merely to shift the definition from one channel to another, or to spread the same definition between two subsections.” (*Id.* at 15) Thus, the only other court that has decided whether filings on PAIR can trigger the amended public disclosure bar agrees with this Court that the answer is “no.”³

In their pending motion, Defendants urge the Court to certify its Opinion and Order for interlocutory appeal under 28 U.S.C. § 1292(b) because there supposedly is an increasing “divergence” of opinion from the courts whether information disclosed in patent prosecutions or IPRs are qualifying public disclosures under the FCA. In making their argument, Defendants rely solely on the out-of-Circuit decision in *Silbersher v. Valeant Pharms. Int’l, Inc.*, 445 F. Supp. 3d 393, 405-06 (N.D. Cal. 2020), *appeal pending* Nos. 20-16176 and 20-16256 (9th Cir.). In that case, the district court held that the second prong of the public disclosure bar sweeps in every Federal hearing, whether the government was a party or not, and therefore includes every IPR (along with, of course, every federal civil case between private parties, and every other administrative hearing between private parties). *See id.* at 406. In other words, the district court in *Valeant* embraced an interpretation of the statute that explicitly renders the first prong of the public disclosure bar a nullity. That decision is on appeal now; the appeal has been fully briefed and is awaiting oral argument.

Contrary to Defendants’ suggestion about divergence of opinion, there is an emerging consensus that *Valeant* is unpersuasive and was incorrectly decided—which is sensible because, as the Third Circuit recently held when construing the FCA, courts “must assume that every word in a statute has meaning and avoid interpreting part of a statute so as to render another part superfluous.” *Polansky v. Exec. Health Res. Inc.*, 17 F.4th 376, 385-86 (3d Cir. 2021) (cleaned

³ The Court also rejected Defendants’ arguments on the merits, but Defendants do not seek certification of the Court’s holding on those issues. (Mot., at 7)

up). More specifically, no authority within the Third Circuit agrees with *Valeant*; and *Allergan* disagreed with *Valeant* within the Ninth Circuit. *See* 506 F. Supp. 3d at 807 (explaining that “the *Valeant* court’s interpretation . . . results not just in a partial overlap but in virtually total nullification of the language that Congress added to romanette (i) of the public disclosure bar in 2010).”

When *Valeant* was decided, the public disclosure issue it decided was one of first impression anywhere in the country, and the court decided that case without the benefit of the thorough and persuasive reasoning in *Allergan* and in this case. The legal landscape has changed significantly since *Valeant* was decided, and those subsequent developments confirm that *Valeant* no longer gives rise to a substantial disagreement (even if it might have pre-*Allergan*).

Tellingly, Defendants apparently don’t believe *Valeant* is persuasive now, either, because they implicitly rejected its holding when briefing their motion to dismiss. (*See* Section I(C), *infra*) And when appealing *Allergan*, the defendants/appellants in that case similarly distanced themselves from *Valeant* and instead took a position inconsistent with *Valeant*’s central holding. (*Ibid.*) Further, when this Court agreed with *Allergan* and disagreed with *Valeant*, it did so without indicating any substantial doubt that the law in the Third Circuit would hold otherwise. Defendants therefore are simply wrong to suggest that there is a substantial ground for a difference of opinion in the Third Circuit concerning the Court’s Opinion and Order. Beyond that, Defendants also fail to satisfy the other requirements for an interlocutory appeal under § 1292(b), because they fail to show a “controlling” question of law, either legally or practically; or that an immediate appeal would likely advance the ultimate termination of the litigation.

Finally, oral argument in the *Allergan* appeal occurred two weeks ago on January 10, 2022, and the case has been fully submitted to the Ninth Circuit. (No. 21-15420, DE 66) Therefore, should the Court find any merit in Defendants’ argument and otherwise be inclined to certify an interlocutory appeal and issue a stay, the Court nevertheless should consider denying Defendants’ motion without prejudice to renewal after the Ninth Circuit’s decision in *Allergan*. If the Ninth Circuit affirms the district court’s decision, then it will have implicitly overruled *Valeant*, and there

would be no further doubt there is no “substantial” basis to disagree with the Court’s Opinion and Order.

ARGUMENT

I. The Court Should Decline to Certify the Order for Interlocutory Appeal

A. Interlocutory Appeal is Reserved for Exceptional Circumstances

In general, an appellate court should not review a district court ruling until after entry of final judgment. *See* 28 U.S.C. § 1291. Because there is a “strong policy against departing from the final judgment rule,” the courts in this Circuit require a showing of “exceptional circumstances” to warrant “application of § 1292(b).” *Durr Mech. Constr., Inc. v. PSEG Fossil, LLC*, No. CV1810675-KM-CLW, 2021 WL 1040510, at *2 (D.N.J. Mar. 18, 2021) (internal citations omitted); *Hulmes v. Honda Motor Co.*, 936 F. Supp. 195, 208 (D.N.J. 1996), *aff’d*, 141 F.3d 1154 (3d Cir. 1998) (interlocutory appeal is to be “‘used sparingly in exceptional’ cases”) (citation omitted).

The courts’ “hostility towards piecemeal appeals” finds sound basis in logical and practical considerations. *Bachowski v. Usery*, 545 F.2d 363, 369 (3d Cir. 1976). The “majority of trial court rulings are affirmed,” and interlocutory appeals “could very well result in prolonging, rather than promptly terminating an action.” *Ibid.* (internal citation omitted). Moreover, if interlocutory appeals are too easily granted, such appeals “could possibly be used to harass parties with lesser resources, and to drive them into submission.” *Ibid.*

To certify an order for appeal, the court must find (1) that the order of appealability involves a controlling question of law, (2) as to which there is a substantial ground for a difference of opinion, and (3) that an immediate appeal may materially advance the ultimate termination of the litigation. *See* 28 U.S.C. § 1292(b); *ADP, LLC v. Ultimate Software Grp., Inc.*, No. CV168664-KM-MAH, 2018 WL 1838003, at *3 (D.N.J. Apr. 17, 2018) (internal citations omitted). The movant bears the burden of proof. *Consumer Fin. Prot. Bureau v. Navient Corp.*, 522 F. Supp. 3d 107, 113 (M.D. Pa. 2021). Even if all three criteria are met, certification is not mandatory, but left

to the sound discretion of the court. *ADP*, 2018 WL 1838003, at *3 (citing cases). Use of immediate interlocutory appeals is “not intended merely to provide review of difficult rulings in hard cases.” *United States Rubber Co. v. Wright*, 359 F.2d 784, 785 (9th Cir. 1966).

B. The Public Disclosure Issue is Not a Controlling Question of Law

The first prong of the Section 1292(b) inquiry is not satisfied, because there is no appeal-worthy, “controlling question” that is “serious to the conduct of the litigation, either practically or legally.” *Durr*, 2021 WL 1040510, at *2 (quotation marks omitted). While the public disclosure questions identified by Defendants are questions of law, they are not dispositive. A resolution in Defendants’ favor might not advance the litigation at all because Plaintiff may still pursue his claims if he is an “original source” possessing “knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions.” *See* 31 U.S.C. § 3730(e)(4).

This Court did not reach that question, and it is unlikely that the Third Circuit would do so in the first instance because the question of whether a relator’s knowledge “materially adds to” the publicly disclosed allegations or transactions is a fact issue that should not be resolved on a Rule 12 motion, much less on interlocutory appeal. *Cf. United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh*, 728 F. App’x 101, 104-05 (3d Cir. 2018).

Even if Defendants won their hypothetical interlocutory appeal, we would likely find ourselves exactly where we are now (just past the pleading stage), after more than a year of additional delay. Thus, these questions should not be deemed “controlling,” and Defendants’ request for interlocutory appeal can be denied on this basis alone.

C. Defendants Have Failed to Establish Substantial Ground for a Difference of Opinion as to the Public Disclosure Bar

Defendants’ argument hinges on their assertion that *Valeant* demonstrates a substantial ground for a difference in opinion, notwithstanding the fact that this Court and *Allergan* have disagreed with its holding. Defendants’ argument can be rejected outright, because they fail to provide any difference of opinion within the Third Circuit: The “substantial ground for difference of opinion must be within the Third Circuit.” *Hu v. BMW of N. Am. LLC*, No. CV184363KMJBC,

2021 WL 1138123, at *3 (D.N.J. Mar. 24, 2021), citing *Cosimano v. Twp. of Union*, 2017 WL 4790381 at *2 (D.N.J. Oct. 23, 2017). Moreover, the fact that an appeal in this case may present a question of first impression before the Third Circuit is not, by itself, “sufficient to show that the question is one on which there is a substantial ground for difference of opinion.” *Cosimano*, 2017 WL 4790381 at *2.

There is no “substantial” ground for a difference of opinion under Third Circuit law. This Court was manifestly correct in holding that Defendants’ statutory construction effectively would nullify Congress’s 2010 amendments to the FCA limiting the first channel to only those proceedings in which the Government was a party. (DE 179, at 13-16) Moreover, Defendants’ interpretation would impermissibly add words to the statute (e.g., “adjudicative” or “adversarial” to the first channel; and “inquisitorial” and “non-adjudicative” to the second channel).

Defendants’ argument rests on the *Valeant* decision, but the legal landscape has changed materially since *Valeant* was decided. Defendants’ arguments to the Court in their motion to dismiss belie any sincere belief that *Valeant* currently creates a “substantial” ground for disagreement with the Court’s Opinion and Order under Third Circuit law post-*Allergan*. In Defendants’ motion to dismiss, they implicitly conceded it would be incorrect to construe channel (ii) in a manner that would nullify the Government-as-party-limitation that Congress imposed on channel (i). Defendants therefore argued that “Channel (ii) thus describes non-adjudicative, administrative activities wherein the Government plays an investigative or inquisitorial role.” (MTD, DE 128-1, at 16) This is directly contrary to the central holding in *Valeant*, which held that that the PTAB’s decisions in an IPR fell within channel (ii), even though the PTAB is an “adjudicative body” that conducts IPR “trials” before “patent judges.” *Valeant*, 445 F. Supp. 3d at 406.

Defendants can’t be faulted for having distanced themselves from *Valeant* when framing their arguments in their motion to dismiss, because it’s clear that *Valeant* is contrary to the law in this Circuit. Even the defendants/appellants in *Allergan* implicitly conceded that *Valeant* was wrongly decided. In the *Allergan* appeal, the defendants/appellants told the Ninth Circuit that “all

agree that the second prong [31 U.S.C. § 3730(e)(4)(A)(ii)] does not govern hearings covered by the first [31 U.S.C. § 3730(e)(4)(A)(i)].” (No. 21-15420, DE 50, at 2) In so arguing, the defendants/appellants in *Allergan*—similarly to Defendants here—essentially admitted that *Valeant* must be wrong in holding that “adversarial” and “adjudicative” IPR proceedings were covered by the second channel of the public disclosure bar even though they were specifically excluded under the first channel. *See Valeant*, 445 F. Supp. 3d at 406.

In summary, Defendants’ arguments before this Court implicitly acknowledge that *Valeant*’s central holding is inconsistent with Third Circuit law (and sound principles of statutory construction in general); and the *Allergan* defendants/appellants effectively concede that *Valeant* is indefensible under Ninth Circuit law. Nobody, not even defendants, is willing to argue that *Valeant* was correctly decided under any Circuit’s law, and *Valeant* has never been cited anywhere for its relevant holding concerning the public disclosure bar, except for *Allergan* and this Court, which have disagreed with it. Defendants’ reliance on *Valeant*, therefore, is insufficient to establish a “substantial” difference in opinion under Third Circuit law; to the contrary, the subsequent analyses of *Valeant* confirm that there is no substantial reason to doubt this Court was correct in its Opinion and Order.

In reality, what Defendants want to do is easy enough to see: they want to use the plainly erroneous—and appealed but not yet overruled—decision in *Valeant* to bootstrap an immediate interlocutory appeal so that they can have another chance to make arguments that are different from the *Valeant* holding. But no court has ever accepted *Defendants*’ view of the law—and so there is no *substantial* basis for a difference of opinion about the arguments *they* are making. And *Valeant* is so plainly wrong that there is no substantial basis for a difference of opinion about that case’s holding, either.

D. An Immediate Appeal Will Not Materially Advance the Ultimate Termination of the Litigation

Certification to the Court of Appeals would materially advance the ultimate termination of the litigation where, “if the trial court decision were reversed on appeal, the litigation would then

end.” *Harter v. GAF Corp.*, 150 F.R.D. 502, 518 (D.N.J. 1993). As explained in Section I(B), *supra*, even if the Opinion and Order were reversed on appeal, litigation would have to proceed to determine the factual issues surrounding Plaintiff’s original source status. This litigation would not end. On the other hand, if litigation is allowed to proceed expeditiously, the public disclosure issue could easily be “mooted by subsequent developments in the litigation.” *ADP*, 2018 WL 1838003, at *5.

Moreover, given the likelihood that the Court’s Opinion and Order would be affirmed on appeal, it is much more likely that an interlocutory appeal would “delay” rather than “hasten the day when the merits can finally be resolved.” *Ibid*.

Finally, if the Court were to find merit in Defendants’ argument and otherwise be inclined to certify an interlocutory appeal and issue a stay, the Court should still deny Defendants’ motion without prejudice to renewal after the Ninth Circuit’s decision in *Allergan*. An interlocutory appeal could delay this case—which was originally filed in 2017—for an additional year or more. On the other hand, it is reasonable to expect the Ninth Circuit to decide the *Allergan* appeal within the next few months. The median time for appeals to be decided in the Ninth Circuit from the date of oral argument to final decision is 1.7 months; and from the filing of a notice of appeal to final decision is 12.5 months. Courts of Appeals Judicial Business, Table B-4 (Sept. 30, 2020), available at https://www.uscourts.gov/sites/default/files/data_tables/jb_b4_0930.2020.pdf (last accessed Jan. 21, 2022). Oral argument for the *Allergan* appeal was held on January 10, 2022, which means that the Ninth Circuit likely could issue its decision within a few months or less. If the Ninth Circuit affirms the district court’s decision, then it will have implicitly overruled *Valeant*, and there would then be no doubt that there is no “substantial” basis to question this Court’s Opinion and Order. We would then have avoided a long and unnecessary delay from an interlocutory appeal.

II. The Court Should Decline to Stay this Action

Whether to stay this case pending an interlocutory appeal is a matter committed to this Court’s sound discretion. “A stay is not a matter of right, even if irreparable injury might otherwise result.” *Nken v. Holder*, 556 U.S. 418, 433–34 (2009) (*quoting* *Virginian R. Co. v. United States*,

272 U.S. 658, 672 (1926). “It is instead ‘an exercise of judicial discretion,’ and ‘[t]he propriety of its issue is dependent upon the circumstances of the particular case.’” *Nken*, 556 U.S. at 433-34 (quoting *Virginian R. Co.*, 272 U.S. at 672-673). The Supreme Court has articulated a four-factor test for whether a stay should issue in any particular case: “(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.” *Nken*, 556 U.S. at 434. These factors are measured under a “‘general balancing’ or ‘sliding scale’ approach where, for example, a weaker showing on the merits require greater proof for the remaining factors. *See In re Revel AC, Inc.*, 802 F.3d 558, 569 (3d Cir. 2015).

Here, Defendants do not even attempt to argue they have a strong likelihood of success on the merits. At most, Defendants contend their proposed appeal would “raise novel questions of statutory interpretation that are subject to disagreement among reasonable jurists.” (Mot. at 20.) For the same reasons that Defendants have failed to establish there is substantial ground for difference of opinion on the specific public disclosure questions at issue, Defendants have not shown that there is a “serious question” on the merits warranting a stay. *See* Section I(C), *supra*. This factor weighs heavily against the issuance of a stay.

As to the second and third factors, under the sliding scale approach, Defendants are required not just to demonstrate “irreparable injury,” but that the balance of harms tips sharply in their favor. They have failed to do so. Defendants speculate that discovery will be particularly expansive and burdensome in this case, but there is no reason to believe discovery here will be any more burdensome to Defendants than discovery in other complex litigation of its type, with which Defendants are familiar and to which they are well-equipped to respond. Additionally, as Defendants note (Mot., at 20), they have already produced many of their documents from the underlying patent litigations, so the incremental burden of producing their remaining documents is relatively small. On the other hand, a significant delay will harm not just Plaintiff, but the Federal and state governments on whose behalf this action is brought. As the State of California recognized

in its statement of interest in *Allergan* (quoted in DE 146, at 7), these actions have major importance for government health programs, not only because the government stands to recover billions of dollars in fraudulent overcharges, but also because this action may set an important precedent that would discourage similar overcharges resulting from the misuse of fraudulently-obtained patents. Consequently, the lengthy additional delay Defendants seek could deprive the government of a significant and much-needed financial recovery and delay the development of law that could help curb drug-pricing abuse and expand affordable access to healthcare.

For the same reason, the public interest factor weighs against a stay. The public has a significant interest in prompt resolution of cases, like this one, that “may help lower the price of medicine and the cost of health insurance.” (*Ibid.*) A lengthy stay of this action pending an interlocutory appeal, which would likely last at least a year, would not just delay trial, but would also be likely to significantly delay the chances of a settlement, which is the means by which most cases are resolved. By contrast, Plaintiff and the federal and state governments have an interest in the prompt recovery of the overcharges incurred by them, and a stay likely would delay any such recovery for over a year, with little prospect that such a delay would have made any difference at all. The orderly course of justice weighs in favor of continuing to move this case forward, rather than staying it indefinitely.

The most efficient course, therefore, is to proceed expeditiously with this matter, consistent with the principle underlying Rule 1 of the Federal Rules of Civil Procedure that provides for the “just, speedy, and inexpensive” adjudication of Relator’s claims.

CONCLUSION

Defendants’ Motion to Certify Interlocutory Appeal and for a Stay should be denied in its entirety. In the alternative, should the Court find merit in Defendants’ argument and be otherwise inclined to certify an interlocutory appeal and issue a stay, the Court should nevertheless deny Defendants’ motion without prejudice to renewal after the Ninth Circuit’s decision in *Allergan*.

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